510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:

Company Name :	GEMORE TECHNOLOGY CO., LTD.
Contact person:	Boden S.P. Lai
Address :	11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD., Tan Shui, Taipei Hsien, Taiwan
TEL No. :	886-2-8809-1799
Fax No. :	886-2-8809-1781
E-mail address :	gemore@anet.net.tw

Date of Summary Preparation: January 24, 2006.

2. Device Identification:
Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: Low Back Pain Relief System, model GM310PP, GM320PP, GM321PP, and GM330PP.
Classification: Class II (21 CFR 882.5890)
Product Code: GZJ & NUH

3. Identification of predicate device
The Gemore Low Back Pain Relief System models GM310PP, GM320PP, GM321PP, and GM330PP are of comparable type and are substantially equivalent to the following predicate devices:
- K040512: Limit Function WL/OTC-TENS/Model WL-2403.

4. Device Description:
The Gemore Low Back Pain Relief System, models GM310PP, GM320PP, GM321PP, and GM330PP are non-invasive devices which are intended for over the counter use in temporary relied of pain associated with sore and aching muscles in the lower back due to stain from exercise or normal household and work activities.

The devices contain the following main parts: TENS stimulation unit, Support Belt, Self-adhesive pads, and Snap Cable.

The device can be worn on the low back part of user so as to place the stimulation pads on the treatment location of low back.

The main stimulation function is achieved through the stimulation unit of GM310PP, GM320PP, GM321PP, and GM330PP. Those stimulation units have been cleared for 510(k) before being submitted on this new submission for OTC application. The K-number for these four models are K032720.

For the detail description of these four stimulation models, please refer to the information provided in K032720.

5. Intended Use:
   The models GM310PP, GM320PP, GM321PP, and GM330PP are indicated for over the counter use in the temporary relief of pain associated with sore and aching muscles in the low back due to stain from exercise or normal household and work activities.

   For the indication for use statement, please see the information attached hereafter.

6. Technological characteristics:
   A comparison of the technological characteristics of the Gemore models GM310PP, GM320PP, GM321PP, and GM330PP and the predicate device has been performed. The results of this demonstrate that the Gemore model GM310PP, GM320PP, GM321PP, and GM330PP are equivalent to the marketed predicate device. The differences between the Gemore models GM310PP, GM320PP, GM321PP, and GM330PP and the predicate models are insignificant and do not affect the safety or effectiveness of the device.

7. Performance data:
   Since there is not any significant change in the construction specification for the main stimulation unit GM310PP, GM320PP, GM321PP, and GM330PP, the performance testing reports according to ANSI/AAMI NS4, and the safety testing reports according to EN 60601-1, EN 60601-1-1, and EN 60601-1-2 as mentioned in the previous 510(k) submission documents are still available for this submission.

   For the additional fixing part, the neoprene belt, the bio-compatibility testing report done according to ISO 10993-1 as well as the relevant standards are included in this submission.

8. Conclusions
   Gemore Technology Inc, has demonstrated through its evaluation of the Gemore models GM310PP, GM320PP, GM321PP, and GM330PP that the devices are equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Gemore Technology Co., Ltd.
c/o Boden S.P. Lai
11 FL., NO. 29-5, Sec. 2
Chung Cheng E. RD.
Tan Shui, Taipei Hsien, Taiwan

Re: K060222
Trade/Device Name: Low Back Pain Relief System, model numbers GM310PP, GM320PP, GM321PP, and GM330PP
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: January 27, 2006
Received: January 30, 2006

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

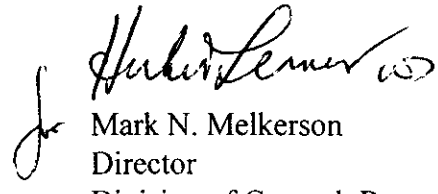
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K060222

Device Name: Low Back Pain Relief System / Model: GM310PP, GM320PP, GM321PP, and GM330PP.

Indications For Use:

- The model GM310PP, GM320PP, GM321PP, and GM321PP are intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060222